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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/573,280	12/21/2006	John C. Hutton	2848-56-PUS	4524

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EXAMINER	
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ART UNIT	PAPER NUMBER
1656	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/573,280	HUTTON ET AL.	
	Examiner	Art Unit	
	Karen Cochrane Carlson, Ph.D.	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 June 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) *1-5,8-10 and 12-17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6, 7, and 11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Applicant's election with traverse of Group III, Claims 6, 7, and 11, in the reply filed on June 13, 2008 is acknowledged. The traversal is on the ground(s) that the Examiner has not provided a basis for why the inventions of Groups II-VIII should not be examined together in accordance to MPEP 1893.03(d). This is not found persuasive because the rules (37 CFR § 1.475(d)) are that when multiple inventions are claimed, the special technical feature of the first invention is compared to the remaining inventions. In the instant case, the special technical feature of the method of Group 1 is related to delaying development of the symptoms of diabetes, while the method of Group 3 is drawn to a method of detecting diabetes, for example. Thus, as noted in the restriction, the method of Group 1 is not used in the method of Groups 2-8. Indeed, all of the methods of Groups 3-8 differ in steps and outcomes, and the IGPR of Group 2 is not novel.

> PCT Rule 13.
> Unity of Invention
> 13.1..Requirement
> The international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention").
> 13.2..Circumstances in Which the Requirement of Unity of Invention Is *>to< Be Considered Fulfilled
> Where a group of inventions is claimed in one and the same international application, the requirement of unity of invention referred to in Rule 13.1 **shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features**. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

> **37 CFR § 1.475** Unity of invention before the International Searching Authority, the International Preliminary Examining Authority and during the national stage.
> (a) An international and a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). **Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features.** The expression "special technical

features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.
(b) An international or a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:
(1) A product and a process specially adapted for the manufacture of said product; or
(2) A product and process of use of said product; or
(3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or
(4) A process and an apparatus or means specifically designed for carrying outthe said process; or
(5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.
(c) If an application contains claims to more or less than one of the combinations of categories of invention set forth in paragraph (b) of this section, unity of invention might not be present.
(d) **If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each of the other categories related thereto will be considered as the main invention in the claims**, see PCT Article 17(3)(a) and § 1.476(c).
(e) The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-17 are currently pending. The Examiner has withdrawn Claims 1-5, 8-10, and 12-17 from further consideration because these claims are drawn to non-elected inventions. Claims 6, 7, and 11, drawn to a method of detecting diabetes via IGRP detection of autoantibodies, are currently under examination.

Benefit of priority is to September 22, 2003.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6 and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In Claim 6, no detecting step is set forth. It is not clear what response from contacting a biological sample from a mammal with an IGRP is to be detected. Without knowing the response to be detected, Claim 6 is incomplete.

In Claim 11, it is not clear what is being measured by RIA, for example, because the response to be detected in Claim 6 is not set forth.

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 6, 7, and 11 are rejected under 35 U.S.C. 101 because the disclosed invention is inoperative and therefore lacks utility.

At page 22, in Example 2, the specification states:

EXAMPLE 2

Test for antibodies to IGRP.

IGRP was investigated as a humoral autoantigen in diabetic human subjects and NOD mice using a series of assays based either upon immunoprecipitation of 35S-labelled *in vitro* translated protein generated from reticulocyte lysates, or ELISAs based on the binding of antibodies to recombinant protein immobilized on microtiter plates or PVDF membranes. **The assays easily detected antibodies from rabbits immunized with an IGRP COOH-terminal peptide or recombinant antigen (antibody dilution l:50 to 1:8000) but failed to demonstrate the presence of autoantibodies in spontaneous diabetic or prediabetic samples, a high proportion of which were positive for one or more other autoantigens (insulin, GAD65 and ICA512).** Other assays in which IGRP was translated *in vitro* with dog pancreatic microsomes to mimic its insertion into membranes and core glycosylation were similarly negative. Thus, any humoral autoimmune response remains

to be characterized despite testing more than 100 diabetic and 50 control human subjects and 50 NOD mice at various stages of diabetes development.

At page 27, in Example 8, the specification confirms the observations of Example 2:

EXAMPLE 8

Studies with mice bearing human MHC diabetes susceptibility genes.

Autoantibody measurements have been uninformative both in the NOD mouse and new onset diabetic patients and it is conceivable that a dominant CD8 response occurs with little involvement of B-cells.

These examples show that contacting a biological sample from a mammal with an IGRP polypeptide does not detect circulating autoantibodies to IGRP in spontaneous diabetic or prediabetic samples taken from 150 diabetic mammals studied. Therefore, a method for detecting insulin dependent diabetes or susceptibility to developing insulin dependent (type I) diabetes by contacting a biological sample from a mammal and contacting the sample with IGRP and detecting autoantibodies to IGRP is inoperative.

Art of Record:

Lieberman et al. (July 8, 2003; Identification of the β cell antigen targeted by a prevalent population of pathogenic CD8+ T cells in autoimmuune diabetes. PNAS 100(14): 8384-8388) teach that IGRP has no known function (page 8387, right col., ~1/4 from the bottom) and that it is an autoantigen targeted by pathogenic CD8+ T cells.

Hutton et al. (July 22, 2003); A pancreatic β cell-specific homolog of glucose-6-phosphatase emerges as a major target of cell-mediated autoimmunity in diabetes.

PNAS 100(15): 8626-8628) cites Lieberman et al. and discusses IGRP as an autoantigen targeted cell-mediated autoimmunity in diabetes.

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Cochrane Carlson, Ph.D. whose telephone number is 571-272-0946. The examiner can normally be reached on 7:00 AM - 4:00 PM, off alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Kathleen Kerr Bragdon can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Karen Cochrane Carlson, Ph.D./
Primary Examiner, Art Unit 1656